

Accreditation -- Preamble

Subpart F - Accreditation of Certifying Agents

This subpart sets forth the requirements for a national program to accredit State and private entities as certifying agents to certify domestic or foreign organic production or handling operations. This subpart also provides that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) the foreign governmental authority that accredited the certifying agent acted under an equivalency agreement negotiated between the United States Government and the foreign government.

This National Organic Program (NOP) accreditation process will facilitate national and international acceptance of U.S. organically produced agricultural commodities. The accreditation requirements in these regulations will, upon announcement of the first group of accredited certifying agents, replace the voluntary fee-for-service organic assessment program, established by AMS under the Agricultural Marketing Act of 1946. That assessment program verifies that State and private organic certifying agents comply with the requirements prescribed under the International Organization for Standardization/International Electrotechnical Commission Guide 65, "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).⁽¹⁾ ISO Guide 65 provides the general requirements that a certifying agent would need to meet to be recognized as competent and reliable. That assessment program was originally established to enable organic certifying agents in the absence of a U.S. national organic program to comply with European Union (EU) requirements beginning on June 30, 1999. That assessment program verifies that State and private organic certifying agents are operating third-party certification systems in a consistent and reliable manner, thereby facilitating uninterrupted exports of U.S. organic agricultural commodities to the EU. ISO Guide 65 was used as a benchmark in developing the accreditation program described in this final rule. Certifying agents accredited under the NOP that maintain compliance with the Act and these regulations will meet or exceed the requirements of ISO Guide 65; therefore, the organic assessment program is no longer needed.

Participation in the NOP does not preclude the accredited certifying agent from conducting other business operations, including the certification of agricultural products, practices, and procedures to standards that do not make an organic claim. An accredited certifying agent may not, however, engage in any business operations or activities which would involve the agent in a violation of or in a conflict of interest under the NOP.

Description of Regulations

The Administrator will accredit qualified domestic and foreign applicants in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify domestic or foreign production or handling operations as certified organic operations. Qualified applicants will be accredited for 5 years.

Application Process

Certifying agents will apply to the Administrator for accreditation to certify production or handling operations operating under the NOP. The certifying agent's application must include basic business information, must identify each area of operation for which accreditation is requested and the estimated number of each type of operation to be certified annually, and

must include a list of each State or foreign country where it currently certifies production or handling operations and where it intends to certify such operations. Certifying agents must also submit personnel, administrative, conflict of interest, current certification, and other documents and information to demonstrate their expertise in organic production or handling techniques, their ability to comply with and implement the organic certification program, and their ability to comply with the requirements for accreditation. Certifying agents planning to certify production or handling operations within a State with an approved State organic program (SOP) must demonstrate their ability to comply with the requirements of the SOP.

The administrative information submitted by the applicant must include copies of its procedures for certifying operations, for ensuring compliance of its certified operations with the Act and regulations, for complying with recordkeeping requirements, and for making information available to the public about certified operations. The procedures for certifying operations encompass the processes used by the certifying agent to evaluate applicants, make certification decisions, issue certification certificates, and maintain the confidentiality of any business information submitted by the certified operation. The procedures for ensuring compliance of the certified operations will include the methods used to review and investigate certified operations, for sampling and residue testing, and to report violations.

The personnel information submitted with the application must demonstrate that the applicant uses a sufficient number of adequately trained personnel to comply with and implement the organic certification program. The certifying agent will also have to provide evidence that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. They must also show that all persons who review applications for certification perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and that all parties responsibly connected to the certifying agent have revealed existing or potential conflicts of interest.

Applicants who currently certify production or handling operations must also submit a list of the production and handling operations currently certified by them. For each area in which the applicant requests accreditation, the applicant should furnish copies of inspection reports and certification evaluation documents for at least three operations. If the applicant underwent any other accrediting process in the year previous to the application, the applicant should also submit the results of the process.

Certifying agents are prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. This requirement does not apply to voluntary education programs available to the general public and sponsored by the certifying agent.

The Administrator will provide oversight of the fees to ensure that the schedule of fees filed with the Administrator is applied uniformly and in a nondiscriminatory manner. The Administrator may inform a certifying agent that its fees appear to be unreasonable and require that the certifying agent justify the fees. The Administrator will investigate the level of fees charged by an accredited certifying agent upon receipt of a valid complaint or under compelling circumstances warranting such an investigation.

Statement of Agreement.

Upon receipt of the certifying agent's application for accreditation, the Administrator will send a statement of agreement to the person responsible for the certifying agent's day-to-day operations for signature. The statement of agreement affirms that, if granted accreditation as

a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part. Accreditation will not be approved until this statement is signed and returned to the Administrator.

The statement of agreement will include the applicant's agreement to accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500 and the applicant's agreement to refrain from making false or misleading claims about its accreditation status, the USDA accreditation program, or the nature or qualities of products labeled as organically produced. Further, the statement will include the applicant's agreement to pay and submit the fees charged by AMS and to comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. Applicants are also required to affirm through this statement of agreement that they will: (1) conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services; and (2) have an annual program review conducted of their certification activities by their staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.

A private entity certifying agent must additionally agree to hold the Secretary harmless for any failure on the agent's part to carry out the provisions of the Act and regulations. A private entity certifying agent's statement will also include an agreement to furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. Such security will be in an amount and according to such terms as the Administrator may by regulation prescribe. A private entity certifying agent must agree to transfer all records or copies of records concerning its certification activities to the Administrator if it dissolves or loses its accreditation. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent. A private entity certifying agent must also agree to make such records available to any applicable SOP's governing State official.

Granting Accreditation.

Upon receiving all the required information, including the statement of agreement, and the required fee, the Administrator will determine if the applicant meets the requirements for accreditation. The Administrator's determination will be based on a review of the information submitted and, if necessary, a review of the information obtained from a site evaluation. The Administrator will notify the applicant of the granting of accreditation in writing. The notice of accreditation will state the area(s) for which accreditation is given, the effective date of the accreditation, any terms or conditions for the correction of minor noncompliances, and, for a private-entity certifying agent, the amount and type of security that must be established.

Certifying agents who apply for accreditation and do not meet the requirements for accreditation will be provided with a notification of noncompliance which will describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. If the applicant is successful in its rebuttal or provides acceptable evidence demonstrating correction of the noncompliances, the NOP Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. If the applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal by the date specified in the notification of noncompliance, or is unsuccessful in its rebuttal, the Program Manager will issue a written

notification of accreditation denial to the applicant. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time or file an appeal of the denial of accreditation with the Administrator by the date specified in the notification of accreditation denial.

Once accredited, a certifying agent may establish a seal, logo, or other identifying mark to be used by certified production and handling operations. However, the certifying agent may not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification. The certifying agent also may not require compliance with any production or handling practices other than those provided for in the Act and regulations as a condition for use of its identifying mark. However, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Administrator, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

Site Evaluations.

One or more representatives of the Administrator will perform site evaluations for each certifying agent in order to examine the certifying agent's operations and to evaluate compliance with the Act and regulations. Site evaluations will include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. A site evaluation of an accreditation applicant will be conducted before or within a reasonable time after issuance of the applicant's notification of accreditation. Certifying agents will be billed for each site evaluation conducted in association with an initial accreditation, amendments to an accreditation, and renewals of accreditation. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

As noted above, a certifying agent may be accredited prior to a site evaluation. If the Program Manager finds, following the site evaluation, that an accredited certifying agent is not in compliance with the Act or regulations, the Program Manager will issue the certifying agent a written notification of noncompliance. If the certifying agent fails to correct the noncompliances, report the corrections by the date specified in the notification of noncompliance, or file a rebuttal by the date specified in the notification of noncompliance, the Administrator will begin proceedings to suspend or revoke the accreditation. A certifying agent that has had its accreditation suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

Peer Review Panels.

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not fewer than three members who shall annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61⁽²⁾, General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of: (1) accreditation procedures, (2) document review and site evaluation reports, and (3) accreditation decision documents or documentation. The peer review panel shall report its

finding, in writing, to the NOP Program Manager.

Continuing Accreditation.

An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) a complete and accurate update of its business information, including its fees, and information evidencing its expertise in organic production or handling and its ability to comply with these regulations; (2) information supporting any changes requested in the areas of accreditation; (3) a description of measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) the results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and (5) the required AMS fees.

Certifying agents will keep the Administrator informed of their certification activities by providing the Administrator with a copy of: (1) any notice of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation issued simultaneously with its issuance and (2) a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.

One or more site evaluations will occur during the 5-year period of accreditation to determine whether an accredited certifying agent is complying with the Act and regulations. USDA will establish an accredited certifying agent compliance monitoring program, which will involve no less than one randomly selected site evaluation of each certifying agent during its 5-year period of accreditation. Larger and more diverse operations, operations with clients marketing their products internationally, and operations with a history of problems should expect more frequent site evaluations by USDA. Operations with clients marketing their products internationally will be annually site evaluated to meet the ISO-Guide 61 requirement for periodic surveillance of accredited certifying agents. USDA may also conduct site evaluations during investigations of alleged or suspected violations of the Act or regulations and in followup to such investigations. Such investigations will generally be the result of complaints filed with the Administrator alleging violations by the certifying agent. Compliance site evaluations may be announced or unannounced at the discretion of the Administrator. Certifying agents will not be billed by USDA for USDA-initiated site evaluations conducted to determine compliance with the Act and regulations.

An accredited certifying agent must provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and these regulations. The certifying agent must maintain strict confidentiality with respect to its clients and not disclose to third parties (with the exception of the Secretary or the applicable SOP's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing these regulations except as authorized by regulation. A certifying agent must make the following information available to the public: (1) certification certificates issued during the current and 3 preceding calendar years; (2) a list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years; and (3) the results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years. A certifying agent may make other business information available to the public if permitted in writing by the producer or handler. This information will

be made available to the public at the public's expense.

An accredited certifying agent must maintain records according to the following schedule: (1) records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt; (2) records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and (3) records created or received by the certifying agent pursuant to the accreditation requirements, excluding any records covered by the 10-year requirement, must be maintained for not less than 5 years beyond their creation or receipt. Examples of records obtained from applicants for certification and certified operations include organic production system plans, organic handling system plans, application documents, and any documents submitted to the certifying agent by the applicant/certified operation. Examples of records created by the certifying agent regarding applicants for certification and certified operations include certification certificates, notices of denial of certification, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, notification of suspension or revocation, correspondence with applicants and certified operations, on-site inspection reports, documents concerning residue testing, and internal working papers and memorandums concerning applicants and certified operations. Examples of records created or received by the certifying agent pursuant to the accreditation requirements include operations manuals; policies and procedures documents (personnel, administrative); training records; annual performance evaluations and supporting documents; conflict of interest disclosure reports and supporting documents; annual program review working papers, memorandums, letters, and reports; fee schedules; annual reports of operations granted certification; application materials submitted to the NOP; correspondence received from and sent to USDA; and annual reports to the Administrator.

The certifying agent must make all records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable SOP's governing State official. In the event that the certifying agent dissolves or loses its accreditation, it must transfer to the Administrator and make available to any applicable SOP's governing State official all records or copies of records concerning its certification activities. This requirement for the transfer of records does not apply to a merger, sale, or other transfer of ownership of a certifying agent.

Certifying agents are also required to prevent conflicts of interest and to require the completion of an annual conflict of interest disclosure report by all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. Coverage of the conflict of interest provisions extends to immediate family members of persons required to complete an annual conflict of interest disclosure report. A certifying agent may not certify a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. A certifying agent may certify a production or handling operation if any employee, inspector, contractor, or other personnel of the certifying agent has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. However, such persons must be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of the entity in which they have or have held a commercial interest. The acceptance of payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected is prohibited. However, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign

certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations. Certifying agents are also prohibited from giving advice or providing consultancy services to certification applicants or certified operations for overcoming identified barriers to certification. To further ensure against conflict of interest, the certifying agent must ensure that the decision to certify an operation is made by a person different from the person who conducted the on-site inspection.

The certifying agent must reconsider a certified operation's application for certification when the certifying agent determines, within 12 months of certifying the operation, that a person participating in the certification process and covered under section 205.501(c)(11)(ii) has or had a conflict of interest involving the applicant. If necessary, the certifying agent must perform a new on-site inspection. All costs associated with a reconsideration of an application, including onsite inspection costs, shall be borne by the certifying agent. When it is determined that, at the time of certification, a conflict of interest existed between the applicant and a person covered under section 205.501(c)(11)(i), the certifying agent must refer the certified operation to a different accredited certifying agent for recertification. The certifying agent must also reimburse the operation for the cost of the recertification.

No accredited certifying agent may exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. Accredited certifying agents must accept all production and handling applications that fall within their areas of accreditation and certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any association or group.

Renewal of Accreditation.

To avoid a lapse in accreditation, certifying agents must apply for renewal of accreditation at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The Administrator will send the certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

Following receipt of the certifying agent's annual report and fees and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and regulations and should have its accreditation renewed. Upon a determination that the certifying agent is in compliance with the Act and regulations, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied. Renewal of accreditation will be for 5 years. Upon a determination that the certifying agent is not in compliance with the Act and regulations, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation. Any certifying agent subject to a proceeding to suspend or revoke its accreditation may continue to perform certification activities pending resolution of the proceedings to suspend or revoke the accreditation.

Amending accreditation.

An accredited certifying agent may request amendment to its accreditation at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation, a complete and accurate update of the certifying agent's application information and evidence of expertise and ability, and the applicable fees.

Accreditation - Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) Advice and Consultancy Services. We have amended section 205.501(a)(11)(iv) to clarify that certifying agents are to prevent conflicts of interest by not giving advice or providing consultancy services to applicants for certification and certified operations for overcoming identified barriers to certification. This amendment has been made in response to a commenter who stated that the provisions of section 205.501(a)(11)(iv), as proposed, seemed to preclude the providing of advice and educational workshops and training programs. It was not our intent to prevent certifying agents from sponsoring in-house publications, conferences, workshops, informational meetings, and field days for which participation is voluntary and open to the general public. The provisions as originally proposed and as amended are intended to prohibit certifying agents from telling applicants and certified operations how to overcome barriers to certification identified by the certifying agent. It would be a conflict of interest for a certifying agent to tell an operation how to comply inasmuch as the certifying agents impartiality and objectivity will be lost should the advice or consultancy prove ineffective in resolving the noncompliance. The provisions of section 205.501(a)(11)(iv) are consistent with ISO Guide 61.

To further clarify this issue, we have also amended section 205.501(a)(16) by adding "for certification activities" after the word, "charges."

(2) Conflicts of Interest - Persons Covered. We have amended section 205.501(a)(11)(v) to limit the completion of annual conflict of interest disclosure reports to all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. A commenter recommended amending section 205.501(a)(11)(v) to have it apply to all persons with direct oversight of or participation in the certification program rather than all persons identified in section 205.504(a)(2). Section 205.504(a)(2) includes all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent. We have decided that completion of annual conflict of interest disclosure reports by persons not involved in the certification process or responsibly connected to the certifying agent is unnecessary. As amended, section 205.501(a)(11)(v) includes all persons with the opportunity to influence the outcome of a decision on whether to certify a specific production or handling operation. Completed conflict of interest disclosure reports will be used by certifying agents to identify persons with interests in applicants for certification and certified operations that may affect the impartiality of such persons.

(3) Reporting Certifications Granted. We have amended section 205.501(a)(15)(ii) (formerly section 205.501(a)(14)(ii)) by replacing "a quarterly calendar basis" with "January 2 of each year." A commenter stated that the requirement that certifying agents report certifications that they have granted on a quarterly basis to the Administrator is burdensome. The commenter requested that section 205.501(a)(14)(ii) be amended to require a midyear or end-year reporting. Section 205.501(a)(15)(ii) now requires the certifying agent to submit a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year. Certifying agents can fulfill this

requirement by providing an up-to-date copy of the list of producers and handlers required to be made available to the public by section 205.504(b)(5)(ii).

(4) Notification of Inspector. We have added a new section 205.501(a)(18) requiring the certifying agent to provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and to notify the inspector of the certifying agent's decision relative to granting or denying certification to the applicant site inspected by the inspector. Such notification must identify any requirements for the correction of minor noncompliances. We have made this addition because we agree with the commenter that such information should be provided to the inspector and because the requirements are consistent with ISO Guide 61.

(5) Acceptance of Applications. We have added a new section 205.501(a)(19) requiring the certifying agent to accept all production or handling applications for certification that fall within the certifying agent's areas of accreditation and to certify all qualified applicants, to the extent of their administrative capacity to do so, without regard to size or membership in any association or group. We have made this addition because we agree with the many commenters who requested that certifying agents be required to certify all qualified applicants. We recognize, however, that there may be times when the certifying agent's workload or the size of its client base might make it necessary for the certifying agent to decline acceptance of an application for certification within its area of accreditation. This is why we have included the proviso, "to the extent of their administrative capacity to do so." We have included "without regard to size or membership in any association or group" to address commenter concerns about discrimination in the providing of certification services. This addition is consistent with ISO Guide 61.

(6) Ability to Comply with SOP. We have added a new section 205.501(a)(20) requiring the certifying agent to demonstrate its ability to comply with an SOP, to certify organic production or handling operations within the State. This change, as pointed out by a State commenter, is necessary to clarify that a certifying agent must be able to comply with an SOP to certify production or handling operations within that State.

(7) Performance Evaluation. We have amended section 205.501(a)(6) by replacing "appraisal" with "evaluation" and expanding the coverage from inspectors to persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions. Corresponding amendments have also been made to section 205.510(a)(4). Further, we have amended section 205.501(a)(6) to clarify that the deficiencies to be corrected are deficiencies in certification services. We changed "appraisal" to "evaluation" at the request of a State commenter who pointed out that State inspectors generally perform other duties in addition to the inspection of organic production or handling operations. We concur that this change will help differentiate between the State's employee performance appraisal for all duties as a State employee and the evaluation of certification services provided under the NOP. Expanding the coverage from inspectors to all persons involved in the certification process makes the regulation consistent with ISO Guide 61. Sections 205.505(a)(3) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(6).

(8) Annual Program Evaluation. We have amended section 205.501(a)(7) by replacing "evaluation" with "review" and by replacing "evaluations" with "reviews." A commenter suggested amending section 205.501(a)(7) by replacing the requirement of an annual program evaluation with an annual review of program activities. We agree that "review" is a more appropriate term than "evaluate" since to review is to examine, report, and correct while evaluate is more in the nature of assessing value. We have not, however, accepted that portion of the commenter's suggestion which would have removed the reference to the

review being conducted by the certifying agent's staff, an outside auditor, or a consultant who has the expertise to conduct such reviews. We have not accepted this suggestion because the comment would have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. Another commenter wanted to change the requirement to an annual assessment of the quality of the inspection system. We have not accepted this suggestion because it can be interpreted as narrowing the scope of the review from the full certification program to just the inspection component of the certification program. This commenter would also have limited the review to being conducted by the certifying agent with no requirement that the certifying agent be qualified to conduct the review. We believe that narrowing the scope of the review would be inconsistent with ISO Guide 65. It is also inconsistent with our intent that the entire certification program be reviewed annually. We also received a comment stating that it is a violation of ISO Guide 65 to have staff perform an internal review. We disagree with this commenter. ISO Guide 65 provides that the certification body shall conduct periodic internal audits covering all procedures in a planned and systematic manner. Sections 205.505(a)(4) and 205.510(a)(4) have been amended to make their language consistent with the changes to section 205.501(a)(7).

(9) Certification Decision. We have added a new section 205.501(a)(11)(vi) that requires the certifying agent to ensure that the decision to certify an operation is made by a person different from the person who carried out the on-site inspection. Commenters requested that this provision be added to the requirement that certifying agents prevent conflicts of interest. We concur with the request because it clearly separates the act of inspecting an organic operation from the act of granting certification. This addition is also consistent with ISO Guide 65, section 4.2(f), which requires that the certification body ensure that each decision on certification is taken by a person different from those who carried out the evaluation.

(10) Determination of Conflict of Interest. We have added a new section 205.501(a)(12) addressing situations where a conflict of interest present at the time of certification is identified after certification. Several commenters requested the addition of a provision that, if a conflict of interest is identified within 12 months of certification, the certifying agent must reconsider the application and may reinspect the operation if necessary. We agree with the commenters that the issue of conflicts of interest present at the time of certification but identified after certification need to be addressed in the regulations. Accordingly, we have provided that an entity accredited as a certifying agent must reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under section 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, all costs associated with a reconsideration of application, including onsite inspection costs, must be borne by the certifying agent. Further, a certifying agent must refer a certified operation to a different accredited certifying agent for recertification when it is determined that any person covered under section 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant. Because the certifying agent is responsible for preventing conflicts of interest, the certifying agent must reimburse the operation for the cost of the recertification. Sections 205.501(a)(12) through 205.501(a)(17) have been redesignated as sections 205.501(a)(13) through 205.501(a)(18), respectively.

(11) Financial Security. We published an advanced notice of proposed rulemaking and request for comments regarding financial security in the August 9, 2000, issue of the Federal Register. We issued a news release announcing the Federal Register publication on August 9, 2000. Numerous commenters expressed concern about reasonable security relative to its amount and impact on small certifying agents. A few commenters requested a definition for reasonable security. Others stated that the formula for determining the amount of security

should be published in the Federal Register. The March 13, 2000, NOP proposed rule stated that the amount and terms of reasonable financial security would be the subject of additional rulemaking. The August 9, 2000, advanced notice of proposed rulemaking solicited comments on all aspects of reasonable security and protection of the rights of program participants. We requested comments from any interested parties, including producers and handlers of organic agricultural products, certifying agents, importers and exporters, the international community, and any other person or group. Six questions were provided to facilitate public comment on the advanced notice of proposed rulemaking. Comments addressing other relevant issues were also invited. The questions posed in the advanced notice of proposed rulemaking were:

- (1) From what risks or events might a customer of a private certifying agent require reasonable security?
- (2) What are the financial instrument(s) that could provide the reasonable security to protect customers from these events?
- (3) What dollar amounts of security would give reasonable protection to a customer of a private certifying agent?
- (4) What are the financial costs to private certifiers, especially small certifiers, of providing reasonable security?
- (5) Do the risks or events provided in response to question #1 necessarily require financial compensation?
- (6) Are there situations in which reasonable security is not needed?

Following analysis of the comments received, we will publish a proposed rule on reasonable security in the Federal Register. The public will again be invited to submit comments. The proposed rule will include the proposed regulation, an explanation of the decision-making process, an analysis of the costs and benefits, the effects on small businesses, and an estimate of the paperwork burden imposed by the regulation.

(12) Use of Identifying Mark. We have amended section 205.501(b)(2) to clarify that all certifying agents (private and State) certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations. Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. See also item 17 under Accreditation - Changes Requested But Not Made. This amendment is intended to further clarify our position that no certifying agent (State or private) may establish or require compliance with its own organic standards. It is an SOP, not a State certifying agent, that receives approval from the Secretary for more restrictive requirements. See also item 7 under Accreditation - Clarifications.

(13) Transfer of Records. To address the issues of a merger, sale, or other transfer of ownership, we have added the following to the end of section 205.501(c)(3); "Provided, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent." Commenters suggested amending section 205.501(c)(3) to provide for the transfer of records accumulated from the time of accreditation to the Administrator or his or her designee, another accredited certifying agent, or an SOP's governing State official in a State where such official exists. It was also stated that this section needs to take into account a certifying agent's decision to merge or transfer accounts to another certifying agent in the case of loss of accreditation. Under the NOP, should a certifying agent dissolve or lose its

accreditation, its certified operations will be free to seek certification with the accredited certifying agent of their choice. Accordingly, it would be inappropriate to automatically transfer an operation's records to another certifying agent as requested by the commenters. However, in analyzing the comments, we realized that a provision was needed for a merger, sale, or other transfer of ownership of a certifying agent; thus, the amendment to section 205.501(c)(3). Section 205.505(b)(3) has been amended to make its language consistent with the changes to section 205.501(c)(3).

(14) Fees for Information. We have amended section 205.504(b)(5) by inserting "including any fees to be assessed" after the word, "used." This change is made in response to the question of whether fees may be charged for making information available to the public. It is our intent that certifying agents may charge reasonable fees for document search time, duplication, and, when applicable, review costs. We anticipate that review costs will most likely be incurred when the information requested is located within documents which may contain confidential business information.

(15) Information Available to the Public. We have amended section 205.504(b)(5)(ii) by adding products produced to the information to be released to the public. This addition responds in an alternate way to commenters who wanted the information included on certificates of organic operation. That request was denied; see item 4, Changes Requested But Not Made, under subpart E, Certification. This addition is consistent with ISO Guide 61.

(16) Equivalency of Certification Decisions and Statement of Agreement. We have amended sections 205.501(a)(12) (redesignated as 205.501(a)(13)) and 205.505(a)(1) by deleting the words, "USDA accredited" and "as equivalent to its own," and adding to the end thereof: "accredited or accepted by USDA pursuant to section 205.500." We have made this amendment to clarify that the provision applies to certification decisions by domestic certifying agents as well as foreign certifying agents accredited or accepted by USDA pursuant to section 205.500.

There were many comments in support of section 205.501(a)(12) as written. However some did not agree that certifying agents should have to recognize another agent's decision as equivalent to their own. These commenters want to maintain the right and ability not to use their seal on a product that does not meet their standards. The most strongly voiced comment stated: "delete section 205.501(a)(12) and section 205.505(a)(1). The requirements constitute a "taking" in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade."

We do not concur with the commenters who want to change sections 205.501(a)(12) and 205.505(a)(1). We also do not agree with the comment that sections 205.501(a)(12) and 205.505(a)(1) constitute a taking in violation of the Fifth Amendment and are unnecessary to accomplish the goal of establishing a consistent standard and facilitating trade. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All domestic organic production and handling operations, unless exempted or excluded under section 205.101, must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All domestic certified operations must be certified by a certifying agent accredited by the Administrator. No USDA-accredited certifying agent, domestic or foreign, may establish or require compliance with its own organic standards. Certifying agents are not required to have an identifying mark for use under the NOP. However, if a certifying agent is going to use an identifying mark under the NOP, the use of such mark must be voluntary and available to all of the certifying agent's clients certified under the NOP. Accordingly, we have not changed the requirement that a certifying agent accept the certification decisions made by another USDA-accredited certifying agent. We

have, however, as noted above, amended both sections to require that USDA-accredited certifying agents accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500.

(17) Granting Accreditation. We have made editorial changes to section 205.506 consistent with the suggestion that we replace "approval of accreditation" with "granting of accreditation." In the title to section 205.506, we have replaced "Approval of" with "Granting." In section 205.506(a), we have replaced "approved" with "granted," and in section 205.506(b), we have replaced "approval" with "the granting." We have made these change because, under the NOP, we grant accreditation rather than approve accreditation.

(18) Correction of Minor Noncompliances. We have added a new section 205.506(b)(3) providing that the notification granting accreditation will state any terms and conditions for the correction of minor noncompliances. Commenters requested the addition of language to section 205.506(b) which would clarify that the Administrator may accredit with required corrective actions for minor noncompliances. In the proposed rule, we addressed accreditation subject to the correction of minor noncompliances at section 205.510(a)(3). We agree with commenters that, for the purposes of clarity, this issue should also be addressed in section 205.506 on the granting of accreditation. Accordingly, we have added new section 205.506(b)(3) as noted above. We have also retained the provisions of section 205.510(a)(3), which requires certifying agents to annually report on actions taken to satisfy any terms and conditions addressed in the most recent notification of accreditation or notice of renewal of accreditation. Section 205.506(b)(3) has been redesignated as section 205.506(b)(4).

(19) Denial of Accreditation. We have amended section 205.507 to include noncompliance and resolution provisions originally included by cross-reference to section 205.665(a). This cross-reference created confusion for commenters, regarding section 205.665's applicability to applicants for accreditation because the section does not specifically address applicants. Rather than specifically identifying applicants within section 205.665, we believe the issue is best clarified by addressing noncompliance and resolution within section 205.507. As amended, section 205.507 now states in paragraph (a) that the written notification of noncompliance must describe each noncompliance, the facts on which the notification is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. This rewrite of paragraph (a) also enabled us to eliminate paragraph (b) since its provisions are addressed in amended paragraph (a). The section also provides, at new paragraph (b), that when each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application. We have also clarified the applicant's appeal rights by adding "or appeal the denial of accreditation in accordance with section 205.681 by the date specified in the notification of accreditation denial" to the end of paragraph (c).

(20) Reinstatement of Accreditation. We have amended section 205.507(d) by removing the requirement that a certifying agent that has had its accreditation suspended reapply for accreditation in accordance with section 205.502. In its place, we provide that the certifying agent may request reinstatement of its accreditation. Such request may be submitted at any time unless otherwise stated in the notification of suspension. Amended section 205.507(d) also provides that the certifying agent's request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We have made this change because unlike revocation, suspension does not terminate a certifying agent's accreditation. Accordingly, requiring a new application for accreditation is unnecessary and burdensome on the certifying agent. This change is consistent with changes to sections 205.662(f) and 205.665(g)(1), which were made based on comments received on section

205.662(f).

(21) Ineligible for accreditation. We have amended section 205.507(d) by deleting "private entity" from the third sentence. The amended sentence provides that "A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination." Several commenters recommended deletion of "private entity" so that private certifying agents would be regulated on an equivalent basis with State certifying agents. It is our intent to regulate private and State certifying agents on an equivalent basis. Accordingly, we made the recommended change.

(22) Peer Review. We have amended section 205.509. As amended, the section requires that the Administrator establish a peer review panel pursuant to FACA (5 U.S.C. App. 2 et seq.). The peer review panel will be composed of not less than 3 members who will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the NOP's accreditation decisions. This will be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents and documentation. The peer review panel will report its finding, in writing, to the NOP's Program Manager. We developed this approach to peer review as a means of addressing the suggestions of the commenters and the need for administration of an effective and timely accreditation program.

Many commenters wanted the opening language in the first sentence of section 205.509 changed from "The Administrator may" to the "The Administrator shall" establish a peer review panel to assist in evaluating applicants for accreditation, amendment to an accreditation, and renewal of accreditation as certifying agents. One of the most frequent comments, including a comment by the NOSB, was that peer reviewers should be compensated for their time and expenses. Many commenters believe also that the peer review process should be collaborative. Some commenters who wanted this change recognized that a collaborative process where confidential information was shared could run into problems because FACA (P.L. 92-463, 5 U.S.C. App.) meetings are open to the public. They advised creating a FACA panel but restricting public access during discussion of confidential business information based on 5 U.S.C. Section 522b(c)(4) of the Government in the Sunshine Act.

As requested, amended section 205.509 requires the formation of a peer review panel. Also as requested, peer reviewers, who will serve as a FACA committee, will be reimbursed for their travel and per diem expenses. The reviewers will also work collaboratively. We have not, however, provided for collaborative review of each applicant for accreditation by the peer review panel because of the administrative burden that an outside collaborative review process would place on the NOP. Currently, there are 36 private and 13 State certifying agencies. It is, therefore, likely that USDA will receive approximately 50 applications for accreditation the first year of the program. Given the need to make accreditation decisions in a timely, organized fashion, it would be infeasible to convene a panel of peers for each applicant for accreditation prior to rendering a decision on accreditation. However, as noted above, we have provided that a peer review panel will annually evaluate the NOP's adherence to the accreditation procedures in subpart F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and validate the NOP's accreditation decisions.

We have also amended current section 205.510(c)(3) by removing the reference to reports submitted by a peer review panel to make that section consistent with the rewrite of section 205.509.

(23) Expiration of accreditation. We have added a new section 205.510(c)(1) which provides

that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration. A commenter suggested USDA notification of certifying agents at least 1 year prior to the scheduled expiration of accreditation. We have made the suggested change because we believe notification about 1 year prior to expiration will facilitate the timely receipt of applications for renewal. We have redesignated sections 205.510(c)(1) and 205.510(c)(2) as 205.510(c)(2) and 205.510(c)(3), respectively.

(24) Amendments to Accreditation. We have added a new section 205.510(f) to provide that an amendment to an accreditation may be requested at any time. The application for amendment must be sent to the Administrator and must contain information applicable to the requested change in accreditation. The application for amendment must also contain a complete and accurate update of the information submitted in accordance with section 205.503, Applicant information; and section 205.504, Evidence of expertise and ability. The applicant must also submit the applicable fees required in section 205.640. We have added this new section because we agree with the commenter who expressed concern that the regulations were not clear regarding amendments to accreditation. This addition is consistent with section 205.510(a)(2) which allows certifying agents to request amendment of their accreditation as part of their annual report to the Administrator.

Accreditation - Changes Requested But Not Made

This subpart retains from the proposed rule, regulations on which we received comments as follows:

(1) Accreditation by USDA. A commenter stated that ISO/IEC Guide 61 specifies, but the proposed rule did not specify, the requirements for USDA to assess and accredit certifying agents. The commenter questioned USDA's acceptance internationally as a competent accreditation body. A few commenters requested that USDA provide certifying agents with assurance of international trade acceptance of the USDA's accreditation program prior to implementation of the final rule. We do not believe that it is necessary to include in these regulations detailed procedures by which USDA will operate its accreditation program. USDA has developed its accreditation and certification programs with the intent that they meet or exceed international guidelines. Every country will make its own decision regarding acceptance of this accreditation program. Accordingly, while we do not anticipate problems with acceptance of our accreditation program, we cannot provide assurance against problems as requested by the commenters.

(2) Equivalency at the European Community (EC) Level. A commenter requested confirmation that an equivalency agreement would be negotiated at the EC level since the EC legislation provides for the basic rules while accreditation of certifying agents is a task for each member state. Another commenter pointed out that because Switzerland has the same regulations as the EC, equivalency would have to be done in close coordination with the EC. The commenter went on to say that according to Swiss and European practice, not only the organic product, but also the bodies involved will be mutually accepted. This commenter also stated that, due to Swiss import provisions, brokers must be subject to a certain control. Equivalency will be negotiated between the United States and the foreign government authority seeking the equivalency agreement.

(3) Period of Accreditation. It was suggested that accreditation should be for a 4-year period with full reevaluation occurring once every 4 years and annual surveillance visits in the intervening years. We do not concur with changing the period of accreditation from 5 years to 4 years as suggested. The 5-year period that we have provided that accreditation is consistent with the Act, which provides that accreditation shall be for a period of not to exceed 5 years. The commenter claims that the international norm is for full reevaluations to

take place once every 4 years with annual surveillance visits in the intervening years. ISO Guide 61, section 3.5.1, provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change.

(4) Accreditation by Private-Sector Accreditation Bodies. Numerous commenters wanted language added to section 205.500(c) that would allow private sector accreditation bodies to accredit foreign certifying agents. For example, several commenters suggested adding a provision reading as follows: "The foreign certifying agent is accredited by a private accreditation body recognized by the USDA as defined by an equivalency agreement negotiated between the USDA and the accreditation body." Commenters also wanted us to amend section 205.502(a) to recognize accreditation by private accreditation programs.

USDA is the accrediting body for all accreditations under the NOP. USDA will not recognize nongovernmental accrediting bodies. USDA will recognize foreign certifying agents accredited by a foreign government authority when USDA determines that the foreign government's standards meet the requirements of the NOP or when an equivalency agreement has been negotiated between the United States and a foreign government.

(5) Requirements for Accreditation. Some commenters requested more specificity in the requirements for accreditation. For example, one recommended that section 205.501(a)(1) should include the requirement that inspectors demonstrate completion of a specified training program or internship or ongoing education and/or licensing. Another commenter wanted baseline criteria for denying an application due to expertise. Still others wanted a definition for (1) "experience and training pertaining to organic/sustainable agricultural methods and their implementation on farm or in processing facilities," (2) "trained certifying agent personnel," and (3) "reasonable time." Finally, one wanted recordkeeping and evaluative parameters. AMS does not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenters. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(6) Volunteer Board Members. Some commenters suggested amending section 205.501(a)(5) to include a reference to committees and to expand "sufficient expertise" to "sufficient balance of interests and expertise." The commenters proposed the amendment to create a firewall between those persons involved in decision making and the volunteer board members. However, the purpose of section 205.501(a)(5) is to ensure that the persons used by the certifying agent to assume inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Therefore, we have not made the suggested changes. Conflict of interest guidelines are found at section 205.501(a)(11).

(7) Confidentiality. A commenter stated that Texas law prevents the Texas Department of Agriculture from guaranteeing confidentiality to its clients. Accordingly, the commenter requested that section 205.501(a)(10) be amended by adding to the end thereof: "or as required by State statutes." We have not made the suggested change because the Act

requires that the certifying agent maintain strict confidentiality with respect to its clients under the NOP and not disclose any business-related information concerning such client obtained while implementing the Act. To be accredited under the NOP, certifying agents must fully comply with the requirements of the Act and these regulations. Further, no SOP will be approved which does not comply with the NOP.

(8) Certifying Agent Fees. Several commenters requested that the regulations prohibit royalty formulas (i.e., fees from every certified sale) for certifying agent fees. It is not our intent to regulate how a certifying agent sets its fees beyond their being reasonable and nondiscriminatory.

(9) Conflicts of Interest. We received numerous comments stating that section 205.501(a)(11)(i) was too restrictive and unnecessary due to the provisions of section 205.501(a)(11)(ii) to prevent conflicts of interest. Some argued that these conflict of interest provisions are beyond ISO requirements and place an undue burden on membership based certifying agents and the entities they serve. They requested a conflict of interest policy enabling membership-based certification organizations to continue operating. A commenter suggested that section 205.501(a)(11) be amended to require that a certifying agent's board members sign an affidavit listing potential conflicts of interest, identify issues where an organization decision might help them personally, and exclude themselves from decision-making that would assist them personally. This commenter proposed the amendment for the purpose of creating a firewall between those persons involved in certification decision-making and the volunteer board members.

We do not believe that the conflict of interest provisions are too restrictive. These provisions are very similar to conflict of interest provisions under other USDA programs involving public-private partnerships (e.g., grain inspection). The certifying agent and its responsibly connected parties, including volunteer board members, hold positions of influence over the certifying agent's employees and persons with whom the certifying agent contracts for such services as inspection, sampling, and residue testing. Therefore, we continue to believe that avoiding such conflicts of interest is necessary to maintain the integrity of the organic certification process.

(10) Conflicts of Interest and Prohibition on Certification. A commenter requested that we include an "or" between sections 205.501(a)(11)(i) and 205.501(a)(11)(ii). We have not made the recommended change because both sections must be complied with; they are not mutually exclusive. Section 205.501(a)(11)(i) prohibits the certification of an applicant when the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the applicant for certification, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification. When the certifying agent and its responsibly connected persons are free of any conflict of interest involving the applicant for certification, the applicant may be certified if qualified. However, section 205.501(a)(11)(ii) requires the certifying agent to exclude any person (employees and contractors who do not meet the definition of responsibly connected), including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification.

(11) Gifts and Contributions. Commenters recommended that section 205.501(a)(11)(iii) be amended to allow not-for-profit organizations to accept gifts and contributions from certified operations for those programs not directly related to the certifying agent's organic certification activities. They also wanted it clarified that not-for-profit organizations can accept voluntary labor from certified operations for those programs not directly related to the certifying agent's

organic certification activities. We have not made the requested changes. First, the acceptance of gifts and contributions would constitute a conflict of interest and would be contrary to ISO Guide 61. Certifying agents must have the financial stability and resources to perform their certification duties without relying on gifts and contributions from those they serve. Second, we have not added the requested provision on voluntary labor because section 205.501(a)(11)(iii) already addresses the acceptance of voluntary labor by not-for-profit organizations from certified operations.

(12) Conflicts of Interest - Determination Period. Commenters wanted to increase the conflict determination period from 12 months to 24 months. Some also wanted the period to extend for 2 years after, with the exception of those who have left the employ of the certifying agent or are no longer under contract with the certifying agent.

We disagree with the recommendations calling for a longer precertification conflict of interest prohibition period. We continue to believe that 12 months is a sufficient period to ensure that any previous commercial interest would not create a conflict of interest situation for two reasons. First, this time period is consistent with similar provisions governing conflicts of interest for government employees. Second, section 205.501(a)(11)(v) requires the completion of an annual conflict of interest disclosure report by all personnel designated to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and program evaluation committees, contractors, and all parties responsibly connected to the certification operation. This requirement will assist certifying agents in complying with the requirements to prevent conflicts of interest. We also continue to believe that a longer prohibition period would have the effect of severely curtailing most certifying agents' ability to comply with the Act's requirement that they employ persons with sufficient expertise to implement the applicable certification program. Accordingly, we have not made the recommended change.

The change recommended by the commenters who requested that the conflict of interest determination period extend for 2 years after certification is unnecessary. Certifying agents and their responsibly connected parties, employees, inspectors, contractors, and other personnel are prohibited from engaging in activities or associations at any time during their affiliation with the certifying agent which would result in a conflict of interest. While associated with the certifying agent, all employees, inspectors, contractors, and other personnel are expected to disclose to the certifying agent any offer of employment they have received and not immediately refused. They are also expected to disclose any employment they are seeking and any arrangement they have concerning future employment with an applicant for certification or a certified operation. The certifying agent would then have to exclude that person from work, discussions, and decisions in all stages of the certification or monitoring of the operation making the employment offer. If a certifying agent or a responsibly connected party of the certifying agent has received and not immediately refused an offer of employment, is seeking employment, or has an arrangement concerning future employment with an applicant for certification, the certifying agent may not accept or process the application. Further, certifying agents and responsibly connected parties may not seek employment or have an arrangement concerning future employment with an operation certified by the certifying agent while associated with that certifying agent. Certifying agents and responsibly connected parties must sever their association with the certifying agent when such person does not immediately refuse an offer of employment from a certified operation. Accordingly, we have decided not to include a postcertification prohibition period in this final rule.

(13) False and Misleading Claims. A commenter asked who will determine what is a misleading claim about the nature or qualities of products labeled as organically produced. This same commenter recommended amending section 205.501(a)(13) by removing the prohibition against making false or misleading claims about the nature or qualities of products

labeled as organically produced.

We disagree with this recommendation. Claims regarding accreditation status, the USDA accreditation program for certifying agents, and the nature and quality of products labeled as organically produced all fall under the authority of the Act. Accordingly, USDA will determine what is a misleading claim. We believe that the requirements are needed to prevent the dissemination of inaccurate or misleading information to consumers about organically produced products. We further believe that the change suggested by the commenter would undermine the goal of a uniform NOP by allowing certifying agents to make claims that would state or imply that organic products produced by operations that they certify are superior to those of operations certified by other certifying agents. These requirements would not prohibit certifying agents from sharing factual information with consumers, farmers, processors, and other interested parties regarding verifiable attributes of organic food and organic production systems. Accordingly, we have not made the recommended change to what is now section 205.501(a)(14).

(14) Certifying Agent Compliance With Terms and Conditions Deemed Necessary. A commenter recommended that we remove section 205.501(a)(17). This section requires that certifying agents comply with and implement other terms and conditions deemed necessary by the Secretary. This requirement is consistent with section 6515(d)(2) of the Act, which requires a certifying agent to enter into an agreement with the Secretary under which such agent shall agree to such other terms and conditions as the Secretary determines appropriate. Accordingly, we have not accepted the commenter's recommendation. This requirement is located at current section 205.501(a)(21).

(15) Limitations on the Use of Certifying Agent's Marks. Numerous commenters stated that they wanted USDA to permit higher production standards by private certifying agents. A common argument for allowing higher standards was that practitioners must be allowed to "raise the bar" through superior ecological on-farm practices or pursuit of other social and ecological goals. Some commenters recommended that the language in section 205.501(b)(2) be replaced with provisions that would allow certifying agents to issue licensing agreements with contract specifications that clearly establish conditions for use of the certifying agent's identifying mark.

We believe the positions advocated by the commenters are inconsistent with section 6501(2) of the Act, which provides that a stated purpose of the Act is to assure consumers that organically produced products meet a consistent national standard. We believe that, to accomplish the goal of establishing a consistent standard and to facilitate trade, it is vital that an accredited certifying agent accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500. All organic production and handling operations, unless exempted or excluded under section 205.101 or not regulated under the NOP (i.e., a producer of dog food), must be certified to these national standards and, when applicable, any State standards approved by the Secretary. All certified operations must be certified by a certifying agent accredited by the Administrator. No accredited certifying agent may establish or require compliance with its own organic standards. Accredited certifying agents may establish other standards outside of the NOP. They may not, however, refer to them as organic standards nor require that applicants for certification under the NOP or operations certified under the NOP comply with such standards as a requirement for certification under the NOP. Use of the certifying agent's identifying mark must be voluntary and available to all of its clients certified under the NOP. However, a certifying agent may withdraw a certified operation's authority to use its identifying mark during a compliance process. The certifying agent, however, accepts full liability for any such action.

The national standards implemented by this final rule can be amended as needed to

establish more restrictive national standards. Anyone may request that a provision of these regulations be amended by submitting a request to the NOP Program Manager or the Chairperson of the NOSB. Requests for amendments submitted to the NOP Program Manager will be forwarded to the NOSB for its consideration. The NOSB will consider the requested amendments and make its recommendations to the Administrator. When appropriate, the NOP will conduct rulemaking on the recommended amendment. Such rulemaking will include an opportunity for public comment.

(16) Evidence of Expertise and Ability. A commenter stated that section 205.504, which addresses the documentation necessary to establish evidence of expertise and abilities, requires too much paperwork. We believe the amount of paperwork is appropriate for the task at hand, verifying a certifying agent's expertise in and eligibility for accreditation to certify organic production and handling operations to the NOP. We further believe that the level of paperwork is necessary to meet international guidelines for determining whether an applicant is qualified for accreditation as a certifying agent.

(17) Procedures for Making Information Available to the Public. Comments on section 205.504(b)(5) were mixed. Some commenters felt that the proposal fell short of the OFPA requirement to "Provide for public access to certification documents and lab analysis." Others thought that too much confidential information would be released.

The Act requires public access, at section 2107(a)(9), to certification documents and laboratory analyses pertaining to certification. Accordingly, we disagree with those commenters who requested that such documents not be released to the public. We also disagree with the commenters who contend that the requirement for public disclosure falls short of what is required by the Act. Section 205.504(b)(5) meets the requirements of the Act by requiring the release of those documents cited in section 2107(a)(9) of the Act. The section also authorizes the release of other business information as authorized in writing by the producer or handler.

(18) Accreditation Prior to Site Evaluation. Numerous commenters recommended that we require site visits prior to accreditation. Some commenters cited ISO Guide 61, section 2.3.1, in their arguments for site visits prior to accreditation. ISO Guide 61, section 2.3.1., provides that the decision on whether to accredit a body shall be made on the basis of the information gathered during the accreditation process and any other relevant information. Section 3.3.2 of ISO Guide 61 provides that the accreditation body shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant body before an initial accreditation is granted.

We do not concur with the commenters. These regulations provide for assessment of the applicant's qualifications and capabilities through a rigorous review of the application and supporting documentation. Following this review, an initial site evaluation shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." In cases where the document review raises concerns regarding the applicant's qualifications and capabilities and the Administrator deems it necessary, a preapproval site evaluation will be conducted. We have further provided that a site evaluation shall be conducted after application for renewal of accreditation but prior to renewal of accreditation.

Our purpose in allowing for initial accreditation prior to a site evaluation is to facilitate implementation of the NOP and to provide a means for newly established certifying agents to obtain a client base to demonstrate that they can meet the requirements of the NOP regulations. We believe this is consistent with the intent of ISO Guide 61, section 2.3.1. and fits within its "and any other relevant information" provision. Accordingly, we restate our position that accreditation approval without a site evaluation is appropriate, necessary in the case of established certifying agents that may need to make adjustments in their operations

to comply with the NOP regulations, and necessary in the case of newly established certifying agents who will have to obtain a client base to demonstrate beyond the paperwork that they can meet the requirements of the NOP regulations.

(19) Ineligibility After Revocation of Accreditation. Section 205.507(d) provides that a certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination. A commenter stated that the 3-year period of ineligibility is overly long and effectively puts the certifying agent out of business. The commenter suggested that a 6- to 12-month period might be reasonable. We have not accepted the suggested 6- to 12-month ineligibility period because the Act requires a period of ineligibility of not less than 3 years following revocation of accreditation.

(20) Qualifications of the Site Evaluator. A commenter recommended amending section 205.508(a) to indicate the required qualifications of the site evaluator. We have not accepted the recommendation. We do not believe that it is necessary to specify the required qualifications of site evaluators in these regulations. All USDA employees who will perform site evaluations under the NOP are quality systems auditors trained in accordance with internationally recognized protocols.

(21) Complaint Process. A commenter recommended that section 205.510 include a complaint process for complaints by certified operations regarding the performance of a certifying agent or inspector. The commenter also recommended that section 205.510 include a complaint process for the public should they feel that a certifying agent is not in compliance.

We do not believe that it is necessary to include a complaint process in the regulations. All interested parties are free to file a complaint with an accredited certifying agent, SOP's governing State official, or the Administrator at any time. We will provide guidance to accredited certifying agents and SOP's governing State officials regarding the type of information to gather when receiving a complaint. SOP's governing State officials will include in their request for approval of their SOP information on their collection of complaint information. Certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving certified operations in their procedures for reviewing and investigating certified operation compliance (section 205.504(b)(2)). This will include maintaining records of complaints and remedial actions relative to certification as well as documentation of followup actions. Further, certifying agents will include details regarding the collection of complaint information and the investigation of complaints involving inspectors and other personnel employed by or contracted by the certifying agents in their policies and procedures for training, evaluating, and supervising personnel (section 205.504(a)(1)).

(22) Recordkeeping by Certifying Agents. A commenter stated that the 10-year recordkeeping requirement of section 205.510(b)(2) for records created by the certifying agent regarding applicants for certification and certified operations is excessive. The commenter recommended a 5-year retention period. We have not accepted the recommended 5-year records retention period for records created by the certifying agent regarding applicants for certification and certified operations because the Act requires the retention of such records for 10 years.

(23) Reaccreditation. A commenter recommended that section 205.510(c)(1) be amended to require reaccreditation every 3 years. We have provided that accreditation will be for a period of 5 years. This is consistent with the Act which provides that accreditation shall be for a period of not to exceed 5 years. The commenter believes that a 5-year period is not consistent with ISO Guide 61, section 3.5.1, which provides that the accreditation body shall have an established documented program, consistent with the accreditation granted, for

carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited body continues to comply with the accreditation requirements. We believe that accreditation for 5 years is a reasonable period of time. Further, we believe that a 5-year period of accreditation is consistent with ISO Guide 61 inasmuch as we require an annual evaluation of the certification program; annual review of persons associated with the certification process, including inspectors; annual reporting with a complete and accurate update of information required for accreditation; and one or more site evaluations during the period of accreditation in addition to the initial site evaluation for the period of accreditation. Accordingly, we have not made the recommended change. This requirement is located at current section 205.510(c)(2).

(24) Notice of Renewal of Accreditation. A commenter recommended that section 205.510(d) be amended to include a timeframe within which the Administrator must notify an applicant of its renewal of accreditation. We believe that a mandated timeframe for notifying the applicant of renewal of accreditation is inappropriate. We plan to process all applications for renewal of accreditation in the order in which they are received, to confirm the receipt of each application, and to establish a dialog with the applicant upon confirmation of receipt of an application for renewal of accreditation. The length of the renewal process will depend in large part on the nature of the operation seeking renewal of accreditation. To minimize the chances that an accreditation will expire during the renewal process, we have: (1) provided that the Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year before the date of expiration of the certifying agent's accreditation, (2) required that an application for renewal of accreditation must be received at least 6 months prior to expiration of the certifying agent's accreditation, and (3) provided that the accreditation of a certifying agent who makes timely application for renewal of accreditation will not expire during the renewal process. Accordingly, we have not made the recommended amendment.

Accreditation - Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) Accreditation of Foreign Certifying Agents. A commenter suggested that section 205.500 be amended to provide that if there is a government system operating in a foreign country then the government is the appropriate pathway for that country to apply for accreditation.

USDA will accept an application for accreditation to perform certification activities under the NOP from any private entity or governmental entity certifying agent and accredit such applicant upon proof of qualification for accreditation. USDA will provide for USDA accreditation of certifying agents and acceptance of a foreign government's accreditation of certifying agent within the same country. This maximizes opportunity for certifying agents without the potential for confusion and overlap in documentation. Further, we believe these requirements facilitate world trade.

(2) State Approval of Product From Foreign Countries. A commenter stated that any product making claims of organic agricultural ingredients to be sold in California shall fall under the jurisdiction of the California Organic Program for enforcement, inspection, and certification direction. The commenter further stated that, should any foreign certifying agents be accepted, they too shall be subject to the sovereign rights of the State of California to protect and enforce the laws of the State of California and to protect agricultural claims in this State.

Any organic program administered by a State will have to be approved by the Secretary. Approval of an SOP will be contingent upon the State's agreeing to accept the certification decisions made by certifying agents accredited or accepted by USDA pursuant to section

205.500.

(3) Equivalency. A commenter stated that USDA should declare in section 205.500 that there are no alternative methods of production that meet the Congressional purpose "to assure consumers that organically produced products meet a consistent standard." The commenter went on to state that, if USDA proceeds with equivalency then the regulations should be amended to provide for: (1) no importing until final determination, (2) no final determination until Federal Register publication and public comment, (3) audit of foreign agency and production sites, and (4) revocation of accreditation for violations. The commenter also recommended that foreign certifying agents be reviewed with the same frequency as State certifying agents.

We disagree that there are no alternative methods of production that assure consumers that organically produced products meet a consistent standard. Accordingly, we will negotiate equivalency agreements with foreign governments. A final equivalency agreement will be required before affected product may be imported into the United States and sold, labeled, or represented as organic. Equivalency agreements will be announced to the public through a notice in the Federal Register and a news release. Site evaluations are a possibility. Foreign certifying agents that receive USDA accreditation, rather than recognition through their government, will have to fully comply with the NOP and will be treated the same as domestic accredited certifying agents.

(4) Evaluation of Equivalency. Commenters asked how equivalency would be evaluated and recommended basing equivalency, not on a check of formalities, but on the finding of substantive equivalence and equivalent effectiveness of certifying systems.

The negotiation of an equivalency agreement will involve meetings between representatives of the foreign government seeking equivalency and representatives of USDA's Agricultural Marketing Service and Foreign Agricultural Service. Support will be provided by the Office of the U.S. Trade Representative. The process will also include the review of documents and possibly one or more site evaluations. Equivalency agreements will be announced to the public through a notice in the Federal Register and a news release.

(5) Treatment of Certifying Agents Operating in More Than One Country. A few commenters requested that we amend section 205.500(c) by adding a provision to clarify the issue of how the international activities of foreign or domestic certifying agents will be treated when they operate in more than one country.

We believe that the requested provision is unnecessary. Certifying agents, domestic and foreign, accredited under the NOP will be expected to comply fully with the requirements of the NOP regardless of where they operate. The only exception would be when they operate in a country in which the Secretary has negotiated an equivalency agreement.

(6) Accreditation of Foreign Certifying Agents. A commenter requested that we amend section 205.500(c) to exempt foreign applicants from having to be accredited certifying agents in USDA's program if the exporting country's national organic program meets international standards; e.g, Codex guidelines.

We have provided for USDA accreditation of qualified foreign certifying agents upon application. We have also provided that USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if it determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part. We have further provided that USDA will accept a foreign certifying agent's accreditation to certify

organic production or handling operations if the foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government. These recognitions of foreign government programs, however, do not extend to international standards such as Codex guidelines. In either case, we are recognizing the ability of a foreign government's program to meet U.S. standards, not some other international standard.

(7) States with an Organic Statute. A commenter stated that a State with an organic statute or regulations that does not certify organic producers or organic handlers should not have to be accredited.

The NOP requires the Secretary's approval of SOP's whether or not the State has a State certifying agent. A State may have an SOP but not have a State certifying agent. In this case the SOP must be approved by the Secretary. A State may have a State certifying agent but no SOP. In this case, the State certifying agent must apply for and receive accreditation to certify organic production or handling operations. Finally, a State may have an SOP and a State certifying agent. In this case, the SOP must be approved by the Secretary, and the State certifying agent must apply for and receive accreditation to certify organic production or handling operations.

(8) Nondiscriminatory Services. A commenter wanted the addition of a provision in section 205.501(a) requiring certifying agents to provide nondiscriminatory services. We have not included the suggested addition in this final rule because the provision already exists in section 205.501(d).

(9) Release of Information. A few commenters requested that we amend section 205.501(a)(10) to include a general exclusion allowing the release of any information with the client's permission. We have not included the suggested addition in this final rule because section 205.504(b)(5)(iv) already addresses the allowed release of other business information as permitted in writing by the producer or handler.

(10) Use of the Term, "Certified Organic." In commenting on section 205.501(b)(1), a commenter stated that if the term, "certified organic," is included on a label, it must state by whom, according to Maine State law. We do not believe that the requirements of section 205.501(b)(1) would preclude a certified operation from complying with a State law requiring identification of the certifying agent on a product sold, labeled, or represented as "certified organic." Further, these regulations do not require a certified operation to use the word, "certified," on its label.

(11) Holding the Secretary Harmless. In commenting on the requirements of section 205.501(c)(1), a commenter stated that certifying agents are responsible for representing USDA but seem to have no recourse. Another commenter asked, what happens if a certifying agent is found in violation of the Act but the violation was due to information or direction that came from USDA?

Under the NOP, accredited certifying agents are required to comply with and carry out the requirements of the Act and these regulations. If they fail to do so, they are responsible for their actions or failures to act. This would not be true if the action or failure to act was at the direction of the Secretary.

(12) Self-evaluation of Ability to Comply. A commenter requested that section 205.504 be amended to provide clarity on the baseline requirements that would allow a certifying agent to conduct a self-evaluation to determine its ability to comply. The commenter stated that there should be some type of baseline acceptance of expertise and ability. The commenter

wants details regarding the "training" or "experience" requirements necessary to qualify for accreditation. This commenter also stated that criteria for inspector and reviewer training should be added and enlarged.

We do not believe that it is necessary to present the requirements for accreditation to the extent of detail requested by the commenter. The intent is to provide flexibility to the certifying agents such that they can tailor their policies and procedures to the nature and scope of their operation. The NOP is available to respond to questions and to assist certifying agents in complying with the requirements for accreditation.

(13) Evidence of Expertise and Ability. Commenters stated that important elements of ISO Guide 65 are missing from section 205.504. They cite the maintenance of a complaints register and a register of precedents and provisions for subcontracting and a documents control policy or a document register.

Certifying agents grant certification, deny certification, and take enforcement action against a certified operation's certification. Certifying agents are required to maintain records applicable to all such actions and to report such actions to the Administrator. Certifying agents may contract with qualified individuals for the performance of services such as inspection, sampling, and residue testing. Certifying agents are required to submit personnel information (employed and contracted) and administrative policies and procedures to the Administrator. All such documents must be updated annually. The regulations also require the maintenance of records according to specified retention periods. All of these factors will be considered in granting or denying accreditation. We believe these requirements meet or exceed the ISO Guide 65 guidelines.

(14) Personnel Evidence of Expertise. A commenter inquired about the frequency at which the personnel information, required by section 205.504(a) and used to establish evidence of expertise and ability, is to be updated. Section 205.510 requires that the certifying agent annually submit a complete and accurate update of the information required in section 205.504.

(15) Responsibly Connected. A commenter stated that the term, "responsibly connected," as used in section 205.504(a)(2) is a broad sweep. The commenter believes the term would include everyone they do business with.

Section 205.504(a)(2) requires the certifying agent to provide the name and position description of all personnel to be used in the certification operation. The section assists the certifying agent in meeting the requirement by identifying categories of persons covered by the requirement including persons responsibly connected to the certifying agent. Responsibly connected does not include everyone that the certifying agent does business with. Responsibly connected is defined in the Definitions subpart of this final rule as "any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation." This definition has not changed.

(16) Independent Third-Party Inspectors. A commenter recommended amending section 205.504(a)(3)(I) to provide for the use of independent third-party inspectors. We believe that this recommended amendment is unnecessary since nothing in these regulations precludes a certifying agent from contracting with independent third parties for inspection services.

(17) Response to Accreditation Applicant. A commenter requested that section 205.506(a)(3) be amended to provide a timeframe within which the Administrator has to respond to the accreditation application. While section 205.506(a)(3) identifies the information to be

reviewed by the Administrator prior to the granting of accreditation, we assume the commenter is seeking a specific time limit by which the Administrator will acknowledge receipt of an application for accreditation. In the alternative, the commenter may have been seeking a specific time limit by which the Administrator must grant or deny accreditation. We believe that a regulation-mandated timeframe for notifying the applicant of receipt of an application or for granting or denying accreditation is unnecessary. We plan to process all applications in the order in which they are received, to confirm the receipt of each application upon receipt, and to establish a dialog with the applicant upon confirmation of receipt of an application for accreditation. We will work with each applicant to complete the accreditation process as expeditiously as possible. A firm timeframe, however, cannot be set for granting or denying accreditation due to the anticipated uniqueness of each applicant and its application for accreditation.

(18) Duration of Accreditation and Certification. A commenter asked, "How can certification be essentially in perpetuity and accreditation have a time restraint?" The commenter's question does not indicate a preference for certification or accreditation longevity. The commenter correctly points out that certification and accreditation, both of which must be updated annually, are granted for different time periods. The Act limits the period of accreditation to 5 years but does not establish a limit to the period of certification. We believe the requirement that the certified operation submit an annual update of its organic plan negates the need for a certification expiration date.

(19) Denial of Accreditation. In commenting on section 205.507, a commenter stated that the regulations need to address what happens to a certifying agent's clients when the certifying agent fails to qualify for accreditation on its first attempt.

Section 205.507(c) provides that an applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with section 205.502. Upon implementation of the certification requirements of the NOP, production and handling operations planning to sell, label, or represent their products as organic must be certified by a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. If a producer's or handler's choice of certifying agents does not receive USDA accreditation, the producer or handler must seek and receive certification under the NOP from a USDA-accredited certifying agent before selling, labeling, or representing their products as organic. Producers and handlers not so certified may not sell, label, or represent their products as organic. Any producer or handler who violates this requirement will be subject to prosecution under section 2120 of the Act.

(20) Loss of Accreditation After Initial Site Visit. Commenting on section 205.508(b), a commenter stated the belief that accreditation before a site visit may cause problems if the certifying agent does not meet the requirements and, subsequently, loses its accreditation. We believe the problems will be no greater than will occur at any other time when it becomes necessary to revoke a certifying agent's accreditation, including when it becomes necessary to initiate proceedings to suspend or revoke the certification of one or more of the certifying agent's certified operations. However, just because revocation of a certifying agent's accreditation may be justified, it may not be necessary to suspend or revoke the certification of one or more of its clients. An operation certified by a certifying agent that has lost its accreditation must make application with a new certifying agent if it is going to continue to sell, label, or represent its products as organic.

(21) Prohibition on Certification After Expiration of Accreditation. A commenter stated that, "USDA should allow certifying agents to apply the same provisions to expiration of certification of a certified operation." The provision referenced by the commenter is the section 205.510(c)(1) (current section 205.510(c)(2)) requirement that certifying agents with an expired accreditation must not perform certification activities under the Act and these

regulations. We have not accepted the commenter's request that the same prohibition be applied to production and handling operations with an expired certification because certification does not expire.

(22) Expiration of Accreditation. Many commenters requested that we amend section 205.510(c)(1) to require annual reports and "minivisits." The commenters cited ISO Guide 61, section 3.5.1. We do not believe that annual "minivisits" are necessary to meet the requirements of ISO Guide 61 or to assure compliance with the NOP. One or more site evaluations will be conducted during the period of accreditation. The certifying agent's annual report will be used as a determining factor in whether to conduct a site evaluation. A request for amendment to a certifying agent's area of accreditation will also result in a site evaluation. This requirement is located at current section 205.510(c)(2).

(23) Update and Review of Inspector Lists. In commenting on section 205.510(c)(1) (current section 205.510(c)(2)) several commenters stated that updating and review of inspector lists must occur more frequently than every 5 years. They cited ISO Guide 61, section 3.5.1.

Section 205.510(a)(1) requires that the certifying agent annually update the information required in section 205.504. This includes the inspector information required by paragraphs 205.504(a)(2) and 205.504(a)(3)(i).

1. ISO/IEC Guide 65 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.

2. ISO/IEC Guide 61 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.